Complete Summary

GUIDELINE TITLE

Prevention of Lyme disease.

BIBLIOGRAPHIC SOURCE(S)

American Academy of Pediatrics. Committee on Infectious Diseases. Prevention of Lyme disease. Pediatrics 2000 Jan;105(1 Pt 1):142-7. [46 references]

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Lyme disease

GUIDELINE CATEGORY

Prevention
Risk Assessment

CLINICAL SPECIALTY

Family Practice
Infectious Diseases
Pediatrics

INTENDED USERS

Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

To provide recommendations for preventing Lyme disease, including the use of Lyme disease vaccine

TARGET POPULATION

Persons residing, working or recreating in Lyme disease-endemic areas of the northeastern and north-central United States

INTERVENTIONS AND PRACTICES CONSIDERED

1. Avoidance of tick-infested habitats
2. Personal protective measures, such as specific types of clothing, use of repellents, and frequent checks for tick bites
3. Recombinant outer-surface protein A (rOspA) Lyme disease vaccine (LYMErix™*) as an adjunct to personal protective measures and the early diagnosis and treatment of Lyme disease

Note: Antimicrobial prophylaxis and serologic testing at the time of a tick bite are considered but not recommended.

*Note from the National Guideline Clearinghouse (NGC) and the American Academy of Pediatrics (AAP): As of February 25, 2002 the manufacturer announced that the LYMErix™ Lyme disease vaccine will no longer be commercially available.

MAJOR OUTCOMES CONSIDERED

Safety and efficacy of LYMErix™ in persons aged 15 to 70 years in the United States

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Although the cost of Lyme disease has been evaluated, there are few published cost-effectiveness analyses of using rOspA vaccines to prevent Lyme disease. A recent analysis by the Centers for Disease Control and Prevention (CDC) indicates that the cost of immunizing exceeds the cost of not immunizing unless the incidence of Lyme disease is more than 1% per year. This analysis did not consider the costs of overdiagnosis and incorrect treatment of disorders falsely attributed to Lyme disease. Most endemic states and counties report Lyme disease incidence rates that are well below 1% per year. However, some studies suggest that only 10% to 15% of physician-diagnosed cases of Lyme disease are reported to state authorities in highly endemic areas.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

1. Attempts to minimize exposure to vector ticks in residential areas is encouraged. Heavily tick-infested areas should be avoided, if possible. If not possible, then personal protective measures (e.g., wearing specific types of clothing, use of repellents, frequent checks for ticks), and early detection and treatment of disease manifestations are encouraged.

2. Routine use of antimicrobial agents to prevent Lyme disease after a deer tick bite, even in highly endemic areas, is not recommended. Serologic testing for Lyme disease at the time of a recognized tick bite also is not recommended.
3. Use of Lyme disease vaccine**.
    a. The vaccine should be considered for administration to the following persons who are 15 years of age or older:
        1. Those who reside, work, or recreate in geographical areas of high or moderate risk (see figure 1 in the original guideline document) and whose activities result in frequent or prolonged exposure to vector ticks.
        2. Those who visit geographical areas of high risk (see figure 1 in the original guideline document) during the peak Lyme disease transmission season and whose activities result in frequent or prolonged exposure to vector ticks.
    b. The vaccine may be given to persons who reside, work, or recreate in geographical areas of high or moderate risk and whose activities result in some, but neither frequent nor prolonged, exposure to vector ticks. However, the benefits of vaccine for these persons compared with those of personal protective measures and early treatment of Lyme disease are unclear.
    c. The vaccine is not recommended for the following:
        1. Those who reside, work, or recreate in areas of high or moderate risk but who have minimal or no exposure to infected ticks.
        2. Persons who reside, work, and recreate in geographical areas of low or no risk (see figure 1 in the original guideline document).
        3. Children younger than 15 years of age until data about the safety and immunogenicity of this vaccine in this age group are available and the United States Food and Drug Administration (FDA) has approved the product for use in this age group.
    d. Persons with a history of Lyme disease

        Immunization should be considered for persons with a history of Lyme disease who are at continued high risk. However, persons with antibiotic treatment-resistant Lyme arthritis should not be immunized because of the association between this condition and immune reactivity to outer surface protein A (OspA). Persons with chronic joint or neurologic illness related to Lyme disease, as well as those with second or third degree atrioventricular block were excluded from the phase III safety and efficacy trial, and, thus, the safety and efficacy of Lyme disease vaccine for such persons is unknown.

    e. Simultaneous administration with other vaccines

        The safety and efficacy of the simultaneous administration of recombinant outer surface protein A (rOspA) vaccine with other vaccines have not been established. Administration of recombinant outer surface protein A vaccine should not interfere with the administration of routinely recommended immunizations. If recombinant outer surface protein A vaccine is to be given concurrently with other vaccines, each should be administered in a separate syringe at a separate site.

f. Persons with immunodeficiencies

Data are lacking on the safety and efficacy of recombinant outer surface protein A vaccines in persons with immunodeficiencies. General guidelines for administration of inactivated or subunit vaccines should be followed (see the Red Book [American Academy of Pediatrics. Pickering LK, ed. 2000 Red Book: Report of the Committee on Infectious Diseases. 25th ed. Elk Grove Village, IL: American Academy of Pediatrics, 2000]).

g. Vaccine use in pregnancy

Because the safety of recombinant outer surface protein A vaccine administered during pregnancy has not been established, immunization of women known to be pregnant is not recommended. A vaccine pregnancy registry has been established by SmithKline Beecham Pharmaceuticals. In the event that a pregnant woman is immunized, health care professionals are encouraged to register this immunization by calling the registry at (800) 366-8900, extension 5231 (toll-free in the United States only).

**Note from the National Guideline Clearinghouse (NGC) and the American Academy of Pediatrics (AAP): As of February 25, 2002 the manufacturer announced that the LYMErix™ Lyme disease vaccine will no longer be commercially available.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting each recommendation is not specifically stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Prevention of Lyme disease, including complications such as arthritis

POTENTIAL HARMS

The recombinant outer surface protein A vaccine seems to be safe. In the randomized controlled trial by Steere and coworkers (Steere AC, Sikand VK, Meurice F et al, and the Lyme Disease Vaccine Study Group. Vaccination against Lyme disease with recombinant Borrelia burgdorferi outer-surface lipoprotein A with adjuvant. N Engl J Med. 1998;339:209-215), soreness at the injection site was the most frequently reported adverse event, reported without solicitation by

24% of the recipients of vaccine and 8% of the recipients of placebo (P <.001). Redness and swelling at the injection site also were reported in significantly more recipients of vaccine (2%) than of placebo (1%). In addition, significantly more recipients of vaccine than placebo reported systemic symptoms (e.g., myalgias, achiness, fever, chills), but none of these symptoms was reported by more than 3% of the subjects in either group. These adverse reactions usually occurred within 48 hours after immunization and lasted a median of 3 days. The type and frequency of symptoms 30 days or more after the injections did not differ significantly between recipients of vaccine and placebo. Symptoms were usually mild or moderate in severity, and the severity usually did not increase with subsequent injections. No hypersensitivity reactions were noted. There was no evidence that the recombinant outer surface protein A vaccine exacerbated prior Lyme arthritis, caused arthritis in subjects with a history of Lyme disease or those without such a history, or caused neurologic disease.

The possibility that a recombinant outer surface protein A vaccine could predispose to arthritis in selected persons with a genetic predisposition to this disorder exists, but no evidence of this effect has been noted.

QUALIFYING STATEMENTS

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- The recommendations in this statement do not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.
- The safety and immunogenicity of the vaccine has not been established in persons older than 70 years or younger than 15 years. Studies are in progress to determine the safety of the vaccine for children 5 to 15 years old.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

American Academy of Pediatrics. Committee on Infectious Diseases. Prevention of Lyme disease. Pediatrics 2000 Jan;105(1 Pt 1):142-7. [46 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2000 Jan

GUIDELINE DEVELOPER(S)

American Academy of Pediatrics - Medical Specialty Society

SOURCE(S) OF FUNDING

American Academy of Pediatrics

GUIDELINE COMMITTEE

Committee on Infectious Diseases

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

AAP Policies are reviewed every 3 years by the authoring body, at which time a recommendation is made that the policy be retired, revised, or reaffirmed without change. Until the Board of Directors approves a revision or reaffirmation, or retires a statement, the current policy remains in effect.

GUIDELINE AVAILABILITY

Electronic copies: Available from the American Academy of Pediatrics (AAP) Policy Web site.

Print copies: Available from American Academy of Pediatrics, 141 Northwest Point Blvd., P.O. Box 927, Elk Grove Village, IL 60009-0927.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on June 20, 2001. The information was verified by the guideline developer as of December 5, 2001.

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